

REMARKS

Status of the Claims

Claims 6-23 are currently pending in this application. Claims 1-5 have been canceled. Claims 6-14 have been withdrawn from further consideration by the examiner as being drawn to a non-elected invention. New claims 21-23, drawn to the same invention as claims 15-20, have been added. Thus, claims 15-23 are currently under examination.

Amendments to the Claims

Claims 15-20 have been amended, and new claims 21-23, drawn to the same invention as claims 15-20, have been added. New claims 21-23 and the amendments to the pending claims do not add prohibited new matter.

Support for replacing “vaccine” with “immunogenic composition” in claims 15-20 can be found on page 8, lines 1, 18, and 19.

Support for inserting “lacks all of the V3 loop except” can be found on page 2, lines 14-24.

Support for the amendment to claim 20 can be found on page 4, line 25.

Support for the amendment to claim 21 can be found on page 4, line 26.

Support for the amendment to claim 22 can be found on page 4, lines 26-29.

Support for the amendment to claim 23 can be found on page 3, line 37 to page 4 line 2.

New claims 21-23 drawn to the same invention as claims 15-20 should be grouped with claims 15-20 and examined in this application.

Rejections of the Claims Under 35 U.S.C. § 112, Second Paragraph

Claims 15-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 has been amended to recite that the mutated V3 loop lacks all of the V3 loop except SEQ ID NO: 1. In view of this amendment, the rejection has become moot. Applicants respectfully request withdrawal of the rejection.

Rejections of the Claims Under 35 U.S.C. § 112, First Paragraph

Claims 15-20 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification to enable the skilled artisan to make and/or use the invention.

Claims 15-23, as they stand, are directed to immunogenic compositions. The specification enables immunogenic compositions comprising a recombinant HIV-1 envelope protein comprising a mutated V3 loop, wherein the mutated V3 loop lacks all of the V3 loop except the GPGRAPH (SEQ ID NO: 1) hexamer sequence flanked by the two basal cysteines, and at least one pharmaceutically acceptable vehicle. Specifically, Tables I to IV on pages 10-13 of the specification show that gp160 ΔGPGRAPH protein anchored to liposomes is an immunogen able to induce high titers of antibodies (IgM, IgG, IgA) in mice. Moreover, Tables V to VIII on pages 15, 16, 18, and 19 of the specification show that the antibodies are able to neutralize infectivity in mice. Further, the results of Tables VII and VIII on pages 18 and 19 indicate that the antibodies induced by the immunosome-anchored Δ3-GPGRAPH-gp160 effectively neutralize HIV-1 from primary isolates #03908, #65869, #65965, #65870, #65871, and #3929. The source of these isolates is peripheral blood of human patients infected with HIV-1. The specification provides sufficient working examples showing that the claimed immunogenic compositions induce antibodies that neutralize primary isolates.

It is known that neutralizing antibodies are necessary to obtain protection against a given microorganism and more specifically a virus. It is also known that while CTLs eliminate infected cells, neutralizing antibodies prevent infections. There are various publications which confirm the role of neutralizing antibodies in immunization. If the Examiner would like to review such publications, Applicants will provide them.

Additionally, Applicants respectfully point out that mice are routinely used for evaluating antibodies raised against selected proteins and that neutralizing antibodies are well known for immunoprotection in both animals and humans. There are also various publications that recognize the use of mice as a valuable animal model for investigating antibodies induced by selected proteins. If the Examiner would like to review such publications, Applicants will provide them.

Since the specification provides sufficient working examples and guidance to enable the claimed invention, Applicants respectfully request withdrawal of this rejection.


Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, they are invited to telephone the undersigned at their convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
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